

## **First Announcement**

### **An introduction to Quality Assurance in Genetic Diagnostic Laboratories**

**Molecular Genetics, Cytogenetics, Biochemical Genetics, Newborn screening**

#### **Two interactive workshops each held over two days:**

##### **Workshop 1.**

**Columbo, Sri Lanka**

**Monday February 6<sup>th</sup>, Tuesday February 7<sup>th</sup> 2012**

Local host:

Prof. Vajira H. W. Dissanayake  
Human Genetics Unit  
Faculty of Medicine,  
University of Colombo

##### **Workshop 2.**

**New Delhi, India**

**Thursday February 9<sup>th</sup>, Friday February 10<sup>th</sup> 2012**

Local host:

Prof. Madhulika Kabra  
Division of Genetics, Department of Pediatrics,  
All India Institute of Medical Sciences,  
New Delhi

Quality assurance is central to the safe and efficient operation of all medical laboratories. This workshop will introduce scientists, technicians and managers from genetic diagnostic laboratories to the development and operation of a Quality Management System compliant with international standards. In addition the workshop will consider international guidelines specific to genetic laboratories. There will be a focus on how External Quality Assessment (Laboratory Proficiency Testing) can be used by a laboratory to compare its performance against its peers and improve its practices.

**Topics will include:**

- The place of a Quality Management System in laboratory practice and achieving accreditation
- The international standards for Quality Management – ISO17025/ISO15189
- Guidelines and Regulatory frameworks for Genetic Testing in Europe, Sri Lanka and India
- Concepts in Quality Assurance
- Developing a Quality Management System, the role of the Quality Manager and the Quality team, the individual responsibility of each member of staff.
- Systems for document control
- Test Validation. The role of controls and reference materials
- Laboratory organization related to quality, risk analysis and the role of Internal Quality Control procedures
- External Quality Assessment including EQA for new technologies in :
  - Molecular Genetics
  - Cytogenetics
  - Biochemical Genetics
- Integrating EQA into routine practice
- Practical exercises in internal audit
- Prospects for developing Quality Assurance practices in genetic laboratories Sri Lanka and India

**Sponsors and contributors:**

- The Government of Sri Lanka
- EMQN: The European Molecular Genetics Quality Network
- ERNDIM: Biochemical Genetics EQA
- CEQA: Cytogenetics European Quality Assessment
- The Government of India

**European Faculty:**

- Dr Rob Elles, PhD, FRCPath – Clinical Director, Genetic Medicine, Manchester UK, Board Member, European Molecular Genetics Quality Network.
- Dr David Barton, PhD, DipRCPPath – Chief Scientist, National Centre for Medical Genetics, Dublin, Ireland. Chairman, European Molecular Genetics Quality Network.
- Prof Brian Fowler, PhD – Head of Laboratory, University Childrens' Hospital (UKBB) Basle, Switzerland. Chairman ERNDIM (Biochemical Genetics External Quality Assessment Scheme)
- Dr Ros Hastings, FRCPath - Scheme Co-ordinator Cytogenetics European Quality Assessment (CEQA), Scheme Organiser UK National External Quality Assessment – Clinical Cytogenetics
- Dr Simon Patton, PhD – Quality Manager Genetic Medicine, Manchester UK, Executive Officer European Molecular Genetics Quality Network.